

Single Day Event

Activity Report for Deliverables in 2024
from the Japan eData

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- The contents of this presentation represent the opinions of the individual presenters and do not represent the opinions or positions of the organization to which they belong.
- The contents of this announcement are omitted for convenience of explanation, and may not always contain accurate information.



Japan eData team's activities

- Today, Japan eData team is researching and investigating
 1. The related global PHUSE activities
 2. eData for RWD
 3. The tasks around eData submission



1. The related global PHUSE activities

- Investigating the contents to be introduced in SDE
- Inviting a special guest for presentation at SDE "Implementation of the ICH E9(R1) Estimands Framework Using Data Standards" from Global PHUSE activities
- Sharing of China application experience in SDE

2. eData for RWD

- Researching the eData submission for RWD at the NDA/ Re-examination application in Japan.
 - Research of published materials related to eData submission of RWD [←Here!](#)
 - Survey for some Pharmaceutical companies
 - Summarizing the current situation and the strategy for eData submission of RWD

3. The tasks around eData submission

- Researching CSR's listings in Japan

STUDY #
(Data Set Identification)

LISTING OF PATIENTS WHO DISCONTINUED THERAPY

Centre:

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontin.
Test Drug/ investigational product								Adverse reaction*

-
-
-

Therapy
failure

Treatment	Patient #	Sex	Age	Last Visit	Duration	Dose	Concomitant Medication	Reason for Discontin.
Active Control/ Comparator								

<https://www.pmda.go.jp/files/000156219.pdf>

CSR's listings in Japan

- As CDISC/eData are common, reducing the number of CSR's listings is ongoing in US.
 - Just say no to data listings!
 - <https://onlinelibrary.wiley.com/doi/abs/10.1002/pst.2286>
- How about the situation in Japan?
 - Pilot survey was conducted with the Japan eData team.



Japan eData team's internal survey

- In **7** companies (including 1 CRO), **2** companies have already started the reduction of listings.
- In **5** companies not reducing listings, **2** companies are discussing the reduction of listings.



Who are the users of listings?

- The listings are still useful for the members outside the data science & biometrics groups, especially for the medical writers.
- The regulators use the listings at the inspection.

Effects to reduce listings

- The resource for the listings can be used for more important tasks.
- However, the members outside the data science & biometrics groups, especially the medical writers, need support about eData at the data review.
- In addition, some listings are needed at the inspection and so on.

Join Us?





Member list

Company	Name (mention)
Eli Lilly	Koichi Yamaguchi (山口孝一)
Eli Lilly	Tomohiko Funai (船井友彦)
Novartis	Yasuhiro Iijima (飯島康浩)
Novartis	Eri Sakai (坂井絵理)
Novartis	Takashi Kitahara (北原孝志)
Janssen	Iori Sakakibara (榊原伊織)
Janssen	Noriyuki Shibayama (柴山典之)
Sumitomo Pharma	Rie Kageyama (影山理絵)
Sumitomo Pharma	Shinichi Hotta (堀田真一)

Company	Name (mention)
AstraZeneca	Yasuhiko Ozawa (小澤康彦)
AstraZeneca	Kazuki Fukuzawa (福澤和輝)
A2 Healthcare	Hisae Yagishita (柳下壽栄)
A2 Healthcare	Takafumi Kamon (嘉門貴文)
Biogen	Kayo Inushima (犬嶋嘉代)
Chugai	Keita Takahashi (高橋慶多)
Ono	Yoshiko Kitagawa (喜多川佳子)
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The Global Healthcare Data Science Community

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